Common Data Element (CDE) Management and Deployment in Clinical Trials

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ABSTRACT

The NCI provides the cancer Data Standards Repository (caDSR) to support development and deployment of CDEs in cancer research. The caDSR, part of the NCI caCORE infrastructure, supports data management workflow requirements and adherence to ISO/IEC 11179 metadata standards. CDEs are developed using standard terminology from caCORE vocabulary services, and are then deployed to multi-site clinical trials data management systems. Here we describe the caDSR and how CDEs are managed and deployed in clinical research.

Background

The NCI supports a broad initiative to standardize the common data elements (CDEs) used in cancer research data capture and reporting. Prior to the advent of CDEs, clinicians and researchers designed data elements anew for each particular study. Commonly collected data such as demographics, labs, vital statistics, histopathology and biomarkers were characterized with heterogeneous metadata. Complex metadata requirements, overlapping and competing medical terminology standards, and inconsistent information models presented challenges and obstacles in the drive toward CDE standardization.

NCI has taken measures to overcome these obstacles and enable collaborators to develop a coherent set of CDEs suitable for sharing. Access to the body of existing CDEs as well as means by which to consume of, add to or modify them is needed. The Cancer Data Standards Repository (caDSR) was developed to address these needs. The caDSR implements the ISO/IEC 11179[1] standard for metadata registries. The existing body of CDEs as well as all new ones have been adapted to this standard.

CDE Tools for the caDSR

The caDSR is part of the NCI caCORE infrastructure, and uses caCORE resources to support data standardization. The system includes an administrator web interface for overall system and CDE management activities. In addition, a suite of specialized end user tools simplify the development, management, and deployment of ISO/IEC 11179 compliant CDEs.

The CDE Browser provides public access to caDSR contents for searching, viewing and downloading CDEs in Excel or XML format. The CDE Curation Tool simplifies the effort to achieve ISO/IEC 11179 metadata compliance, minimizing keystrokes and enabling reuse of existing CDE components. Integrated with caCORE Enterprise Vocabulary Services (EVS) the CDE Curation Tool aids developers in consumption of NCI controlled vocabulary and standard terminologies for naming and defining CDEs.

CDEs are deployed in clinical trials on Case Report Forms (CRFs). Several tools together support a multi-site workflow for the review of CRFs for CDE compliance. The CRF Loader is used to take a PDF-based CRF or similar data collection instrument and instantiate electronic format suitable for computerized algorithmic matching against existing caDSR CDEs. The CDE Compliance Review Tool (CRT) performs the algorithmic matching, guiding an experienced CDE reviewer through iterative review and refinement of matched and partially matched CRF elements with existing CDEs. The CDE Compliance Review Response (CCRR) tool allows remotely located CRF submitters to comment upon the CDE reviewer's analysis. The CDE Curation Tool is used to develop new elements if no suitable matches are found.

Once it is agreed that the CRFs for a trial consist of valid CDEs, the forms and their component CDEs are exported for use in research data management systems. Several clinical research data systems are presently deploying CDEs. At the NCI, the Clinical Trials Support Unit (CTSU) and the Cancer Central Clinical Database (C3D) each use CDEs as a basis for research data management.

References

1. ISO/IEC 11179 Specification and standardization of data elements Parts 1-6.